

REMARKS

Claims 1-9 are pending in this application. Claims 1, 2, and 4 have been rejected and claims 3 and 5-9 have been withdrawn from consideration. The Examiner has acknowledged Applicants' election of Group I with traverse. The Examiner has indicated that she would search SEQ ID NOS: 1, 2, and 43 and has made the restriction requirement final.

Applicants have amended claims 1, 2, and 4, and added new claims 10-14. Support for the claim amendments may be found in the specification as follows.

Claim	Support
1	Example 1, page 18
2	Example 1, page 18
4	Page 14, line 25 – Page 15, line 1
10	Example 1, page 18
11	Page 11, lines 2-5.
12	Page 14, line 25 – Page 15, line 1
13	Page 14, line 25 – Page 15, line 1
14	Example 1, page 18

Applicants have also amended the specification to correct a typographical error on page 18. The GenBank Number for *T. paurometabola* was erroneously designated due to a typographical error; the correct number is AF352578, not AF35257. Applicants have amended the specification accordingly, and enclose a copy of the GenBank printout showing this sequence and as evidence of the readily apparent typographical error. A search of GenBank does not identify any sequences with the erroneous number.

No new matter has been added to the application by way of these amendments.

I. Utility Rejection

The Examiner has rejected claim 4 under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory subject matter. The Examiner is concerned that the claimed "gene fragment" is not necessarily isolated from nature.

Applicants have amended claim 4 to recite "an isolated" gene fragment and request that the Examiner withdraw this rejection.

II. Anticipation Rejections

A. Rejection over *Leckie*

The Examiner rejected claim 1 under 35 U.S.C. § 102(b) as allegedly anticipated by *Leckie* et al. (U.S. Patent No. 5,631,130). *Leckie* teaches a 48 nucleotide sequence, which is designated SEQ ID NO: 54 in the cited patent. The Examiner asserts that the presently claimed SEQ ID NO: 1 is completely identical to the corresponding portion of SEQ ID NO: 54 of *Leckie* from positions 8-20.

GGTGTCTCCATCGCCAAGGAGATCGAGCTCGAGGATCCGTACGAGAAG	<i>Leckie</i> (SEQ ID NO: 54)
GGTGTCTCCATCGCCAAGGAGATCGAGCTCGAGGATCCGTACGAGAAG	AC #X95971

The other sequence provided is GenBank Accession No. X95971, the *groEL2* gene from *S. lividans*, a *Streptomyces* species disclosed in the application. The Examiner alleges that given the degree of alignment, the sequence of *Leckie* would be capable of amplifying a *groEL2* gene fragment from *Streptomyces* species.

Applicants have amended claim 1 to recite that the primer consists of SEQ ID NO: 1. Because the *Leckie* sequence is significantly longer than SEQ ID NO: 1, it cannot anticipate the invention of claim 1. Therefore, Applicants request that the Examiner withdraw this rejection.

B. Rejection over *Tokunaga*

The Examiner has also rejected claim 1 under 35 U.S.C. § 102(b) as allegedly anticipated by *Tokunaga*, Microbiology and Immunology, 36(1):55-66 (1992). *Tokunaga* teaches a 45 base pair nucleotide sequence, which aligns with *Streptomyces groEL2* gene as follows.

TCCATCGCCAAGGAGATCGAGCTCGAGGATCCGTACGAGAAGATC	<i>Tokunaga</i>
TCCATCGCCAAGGAGATCGAGCTCGAGGATCCGTACGAGAAGATC	AC #X95971

Again, the comparison is made to the *S. lividans* sequence. Given the degree of alignment, the Examiner alleges that the sequence of *Tokunaga* would be capable of amplifying a *groEL2* gene fragment from *Streptomyces* species.

Applicants have amended claim 1 to recite that the primer consists of SEQ ID NO: 1. Because the *Tokunaga* sequence is significantly longer than SEQ ID NO: 1, it cannot anticipate the invention of claim 1. Therefore, Applicants request that the Examiner withdraw this rejection.

C. Rejection over Brennan

Finally, the Examiner rejected claim 4 under 35 U.S.C. § 102(b) as allegedly anticipated by Brennan (U.S. Patent No. 5,474,796). Brennan allegedly teaches an array comprising all possible 10 mer nucleic acid sequences (see col. 9-10). As claim 4 currently encompasses a genus of fragments of SEQ ID NO: 43, the Examiner alleges that the fragments taught by Brennan anticipate the fragments encompassed by claim 4.

Applicants have cancelled the second instance of "fragment" in claim 4 and the claim now recites isolated *groEL2* gene fragments comprising SEQ ID NO: 43. SEQ ID

NO: 43 is 420 nucleotides long and none of the 10 mer nucleic acid sequences of Brennan can anticipate this significantly longer sequence. Applicants clarification of the scope of claim 4 obviates this rejection and Applicants request that the Examiner withdraw the rejection.

III. Enablement Rejection

The Examiner has rejected claims 1-2 under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a primer *consisting of* SEQ ID NOS: 1 and 2, allegedly does not enable a primer which *comprises* these sequences. The claims are drawn to primers which specifically amplify a *groEL2* gene fragment from *Streptomyces* species. The Examiner alleges that the claims encompass primers which only amplify *Streptomyces* species. The Examiner is concerned that the transition term *comprising* allows for extensions of the recited sequences which could result in amplification of other strains. In other words, the Examiner alleges that it would take undue experimentation to determine what, if any, additional sequences in combination with SEQ ID NOS: 1 and 2 would render the primers specific for *Streptomyces* species, and that the specification does not provide any guidance regarding those additional sequences.

Applicants have limited the scope of claim 1 to SEQ ID NO: 1. Additionally, Applicants have amended the scope of claim 2 to include only additional nucleotides that are the complement of adjacent sequences from *S. lividans* (GenBank No. X95971), *S. albus* (GenBank No. M76658), and *T. paurometabola* (GenBank No. AF352578).

These primers would result in the amplification of the *groEL2* gene in other *Streptomyces* species due to the homology between these sequences. Additionally, claim 14 is limited to the primer being SEQ ID NO: 2. Applicants note on page 4 of the Office Action, the Examiner concedes that the specification is enabling for primers consisting of SEQ ID NOS: 1 and 2.

Furthermore, it would be very easy for the skilled artisan to make and test these primers with additional sequences from the three recited strains. It is well within the skill of the ordinary artisan to prepare such a primer based on these known sequences. The specification also provides detailed examples for DNA extraction from a sample for testing, PCR amplification using the primers of the invention, and purification of the PCR product. (See Example 2, pages 19-21). The specification also teaches a method for sequencing the PCR product and analyzing the results. (See Example 3, pages 21-24). Thus, it would not require undue experimentation to make and use the primers of the invention as claimed.

Applicants have also removed the objected to language that the primers “specifically” amplify the *Streptomyces* sequences. Further, Applicants have clarified the claim scope to recite that the primer amplifies at least one *Streptomyces* species.

Therefore, Applicants request that this rejection be withdrawn.

IV. Written Description Rejection

The Examiner has rejected claims 1, 2, and 4 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description support in the specification. With respect to claims 1 and 2, the Examiner, again, expresses her concerns regarding the

additional sequences that could comprise the primer along with SEQ ID NOS: 1 and 2. The Examiner indicates that given the variance that could be present in the group of primers *comprising* SEQ ID NOS: 1 and 2 are not representative of the larger genus. Furthermore, the Examiner seems concerned that it is not clear which longer primers would be capable of amplifying all *Streptomyces* species *groEL2* gene fragments and which would be specific for *Streptomyces* species.

Applicants have amended claim 1 to recite SEQ ID NO: 1 and claim 2 to recite that the primer may comprise additional sequences derived from the complement of *S. lividans* (GenBank No. X95971), *S. albus* (GenBank No. M76658), and *T. paurometabola* (GenBank No. AF352578). As these sequences (or their complements) are all disclosed in the specification, the claims find written description support in the specification.

With respect to claim 4, the Examiner is similarly concerned that the claims encompass gene fragments comprising SEQ ID NO: 43. The Examiner alleges that the specification does not provide any guidance regarding the additional sequences that could comprise the gene fragment along with SEQ ID NO: 43, and what the meaning of the term derived from a potato scab pathogenic microorganism. Like the rejection of claims 1 and 2, the Examiner alleges that SEQ ID NO: 43 is not representative of the larger genus of gene fragments encompassed by the claims.

The additional sequences of claim 43 are those that may be found in the sequence of a potato scab pathogenic microorganism. The specification states on page 11, that most *groEL2* genes have a 420 nucleotide sequence, but that certain species

have an extra codon added, resulting in a 423 nucleotide sequence. Therefore, the specification contemplates additional nucleotides that originate in the potato scab pathogenic microorganism.

Applicants have also added new claim 11, which recites these two possible fragment lengths. Applicants have further added a product-by-process claim which recites a *groEL2* gen fragment isolated by PCR amplification using the claimed primers. The gene fragment in claim 11 is isolated from a potato scab pathogenic microorganism by using the claimed primers and that any additional nucleotides between the primers would be amplified along with the nucleotides of SEQ ID NO: 43. Finally, Applicants have added new claim 11, which is limited to the fragment being SEQ ID NO: 43.

Applicants request that the Examiner withdraw this rejection.

V. Definiteness Rejection

The Examiner has rejected claim 4 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The Examiner alleges that the phrase “a *groEL2* gene fragment . . . or fragment thereof” is indefinite. The Examiner also objects to the phrase “chosen from.”

In responding to this rejection, Applicants have deleted the second recitation of the term fragment. The claims now encompass an isolated *groEL2* gene fragment.

In response to the Examiner's other concern, Applicants assert that “chosen from” is an acceptable alternative Markush language format. “Selected from the group consisting of” is not the only acceptable alternative language format. MPEP § 2173.05(h) states the proper test: “Alternative expressions are permitted if they present

no uncertainty or ambiguity with respect to the question of scope or clarity of the claims.” The guidance for examination continues: “*One* acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being ‘selected from the group consisting of A, B and C.’” MPEP § 2173.05(h)(I), *citing Ex parte Markush*, 1925 C.D. 126 (Comm’r Pat. 1925) (emphasis added). Other examples of acceptable alternative claim language published by the PTO may be found in the following sources: MPEP Appendix AI (PCT), Example 20, p. AI-44 of the July 1998 edition (“wherein R1 is methyl or phenyl, X and Z are selected from oxygen (O) and sulfur (S).”); *Training Materials For Examining Patent Applications with Respect to 35 U.S.C. Section 112, First Paragraph - Enablement Chemical/Biotechnical Applications*, released August, 1996 (“X selected from A, B, and C”). In sum, the PTO expects and allows alternative claim language other than the strict formulation “selected from the group consisting of” and provides a test for determining proper alternative claim language.

Applying the proper test to Applicants’ claim language, no uncertainty or ambiguity is found. The recited sequences are alternative embodiments of the claimed invention. In order to clarify this aspect of the invention, Applicants have focused claim 4 on SEQ ID NO: 43 and cancelling the other sequences from claim 4. New claim is directed to fragments comprising any one of SEQ ID NOS: 44-61.

VI. Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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GARRETT & DUNNER, L.L.P.

Dated: September 20, 2006

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Reg. No. 43,796

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Range: from to ☐ Reverse complemented strand Features:

☐ 1: [AF352578](#). Reports *Tsukamurella pau...*[gi:13310800]

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LOCUS AF352578 1623 bp DNA linear BCT 13-MAR-2001

DEFINITION *Tsukamurella paurometabola* heat shock protein 60 (hsp60) gene, complete cds.

ACCESSION AF352578

VERSION AF352578.1 GI:13310800

KEYWORDS .

SOURCE *Tsukamurella paurometabola*

ORGANISM *Tsukamurella paurometabola*
Bacteria; Actinobacteria; Actinobacteridae; Actinomycetales; Corynebacterineae; Tsukamurellaceae; Tsukamurella.

REFERENCE 1 (bases 1 to 1623)

AUTHORS Zimmermann,O.S. and Koechel,H.G.

TITLE *Tsukamurella paurometabola* heat shock protein 60 (hsp60) gene

JOURNAL Unpublished

REFERENCE 2 (bases 1 to 1623)

AUTHORS Zimmermann,O.S. and Koechel,H.G.

TITLE Direct Submission

JOURNAL Submitted (23-FEB-2001) Virology, Univ. Goettingen, Kreuzberggring 57, Goettingen D-37075, Germany

FEATURES

source Location/Qualifiers

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· ORIGIN

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